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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,112	08/23/2001	Stephen Donovan	D-2875DIV	1929
33197	7590	12/21/2004	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			KAM, CHIH MIN	
4 VENTURE, SUITE 300			ART UNIT	
IRVINE, CA 92618			PAPER NUMBER	
			1653	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/938,112

**Applicant(s)**

DONOVAN, STEPHEN

**Examiner**

Chih-Min Kam

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20,21,36,37,67-75,77 and 78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36,37,67,68,72,77 and 78 is/are allowed.
- 6) ☒ Claim(s) 20, 21, 69-71 and 73-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 21, 22, 36, 37, 67-75, 77 and 78 are pending.

Applicants' amendment filed October 8, 2004 is acknowledged, and applicant's response has been fully considered. Claims 21, 36, 37, 67, 69-71, 73-75, 77 and 78 have been amended. Therefore, claims 21, 22, 36, 37, 67-75, 77 and 78 are examined.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

2. The previous rejection of claims 69, 73, 74 and 75 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claim, and applicant's response at page 7 in the amendment filed October 8, 2004.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 21 and 22 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The claims are directed to a method for obtaining an agent for treating pain comprising the steps of expressing a clostridial neurotoxin and covalently attaching or recombinantly fusing the clostridial neurotoxin to a target moiety comprising substance P, wherein H<sub>c</sub> has been removed from the clostridial neurotoxin or modified so as to reduce the ability of the clostridial neurotoxin to bind to a receptor for the H<sub>c</sub> at a neuromuscular junction. While the specification indicates that the modified clostridial neurotoxin can be obtained in the protein level, e.g., by removing or modifying the Hc domain of botulinum

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neurotoxin type A and then covalently coupling the remaining toxin to substance P (page 17, lines 9-14), where the clostridial neurotoxin can be recombinantly produced (page 18, lines 9-15); or the modified neurotoxin is recombinantly produced as a fusion protein of clostridial neurotoxin component and a target moiety of substance P (page 18, lines 6-7, 21-24), the specification does not disclose the clostridial neurotoxin having H<sub>c</sub> modified or removed can recombinantly fuse to substance P. The technique of recombinant fusion is only applied to nucleotide level, not to protein level. For these reasons, the claimed invention is inoperative and therefore lacks utility.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as indicated in the section above.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 69, 70, 71 and 73-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69, 70, 71 and 73-75 are indefinite because of the use of the term "substantially identical". The cited term renders the claim indefinite, it is not clear what percentage of sequence identity the expressed clostridial neurotoxin has as compared to a natural clostridial neurotoxin since the specification does not define the term "substantially identical". Claims 73 and 74 are also indefinite as to how a translocation domain (H<sub>N</sub>) or a light chain (L chain) of a clostridial neurotoxin can be substantially identical to the whole clostridial neurotoxin.

#### ***Conclusion***

6. Claims 20, 21, 69-71 and 73-75 are rejected, it appears claims 36, 37, 67, 68, 72, 77 and 78 are free of art and allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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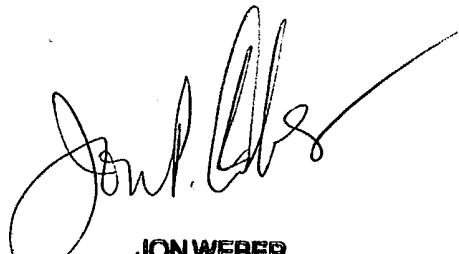
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

CMK

December 16, 2004



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**